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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BRUENJES, CHRISTOPHER P

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,549

Applicant(s)

VISTINS ET AL.

Examiner

Christopher P. Bruenjes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20031117.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to a glove, classified in class 428, subclass 35.7.

II. Claims 18-21, drawn to method of making a glove, classified in class 427, subclass 430.1.

The inventions are distinct; each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as forming an acrylic resin layer and laminating that layer to the substrate body by means of extrusion, rather than coating using an acrylic emulsion.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by

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their different classification, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Vincent Kung on October 25, 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple

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assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-3 and 5-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,895,600 in view of Lee (USPN 5,712,346).

The claims of '600 teach a glove (claim 5 or 14) comprising a substrate body or base polymer and a barrier layer or outer layer overlying at least a portion of the substrate body, the barrier layer comprising an acrylic polymer (claim 1 or 10). The substrate body is formed of synthetic elastomer (claim 2), which is defined in the specification to include polyvinyl chloride (col.8, 1.4-11). The barrier layer is present in an amount that falls within the range of about 4 mass% to about 6 mass% (as taught by the ratio of the thickness of the layers taught in claims 10 and 12). The barrier layer is the outer layer and is in contact with the patient when used as a medical glove. Therefore the barrier layer is a skin-contacting layer.

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The barrier layer is visually distinct from the substrate body because it is formed of a different material. The glove further comprises a donning layer overlying at least a portion of the barrier layer (claim 11). Note the limitation "overlying" does not require that the donning layer be in contact or directly attached to the barrier layer. The donning layer is defined in the specification as being formed of polyurethane (col.8, 1.59-63). The donning layer is defined in the specification as also being a thin layer in the same manner as the barrier layer and therefore would be present in an amount within the claimed range of 0.3 mass% and 1 mass%.

The claims of '600 fail to teach the glass transition temperature of the acrylic polymer. However, the acrylic polymer is defined in the specification as being an acrylic polymer defined in U.S. Pat. No. 5,712,346 to Lee. Lee teaches that one example of the glass transition temperature of the acrylic polymer is 15°C (col.6, 1.13-16). Lee also teaches that the acrylic polymer has multiple glass transition temperatures because the acrylic polymer is a copolymerization of different acrylic monomers so that one glass transition temperature would fall within the claimed range of -10°C and 10°C (col.7, 1.33-45). Lee goes on to teach that the exact glass transition temperature for the acrylic polymer is determined based on the

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desired end result of the acrylic polymer with regards to mold release characteristics and donning characteristics (col.7, 1.60-67). Also if the glass transition temperature is too high flaking will occur and if the glass transition temperature is too low then sticking and blocking will occur (col.8, 1.1-9). One of ordinary skill in the art would have recognized a glass transition temperature for acrylic polymer used in the formation of powder-free medical gloves would be selected through routine experimentation depending on the intended end result of the glove with regards to mold release, donning, flaking, and blocking characteristics, as taught by Lee.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select the glass transition temperature of the acrylic polymer of the claims of '600 within the claimed range depending on the intended end result of the glove especially with regards to mold release, donning, flaking, and blocking characteristics, as taught by Lee.

Regarding claims 14-17, the glove of claims '600 in combination with the teachings of Lee is formed of the same materials as the claimed invention. Therefore, the length of time of the resistance to 70% isopropyl alcohol is a latent property of the glove because the same material must have the

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same properties, and mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention (MPEP 2145).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-12, and 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Williams (US 2003/0115659 A1) with further explanation by Lee (USPN 5,712,346).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the

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invention "by another," or by an appropriate showing under 37 CFR 1.131.

Williams anticipates a glove comprising a substrate body or base polymer and a barrier layer or outer layer overlying at least a portion of the substrate body, the barrier layer comprising an acrylic polymer (see abstract). The substrate body is formed of polyvinyl chloride (col.8, 1.4-11). The barrier layer is present in an amount that falls within the range of about 4 mass% to about 6 mass% (as taught by the ratio of the thickness of the layers taught in claims 10 and 12). The barrier layer is the outer layer and is in contact with the patient when used as a medical glove. Therefore the barrier layer is a skin-contacting layer. The barrier layer is visually distinct from the substrate body because it is formed of a different material. The glove further comprises a donning layer overlying at least a portion of the barrier layer (col.8, 1.51-53 and Figure 3). Note the limitation "overlying" does not require that the donning layer be in contact or directly attached to the barrier layer. The donning layer is formed of polyurethane (col.8, 1.59-63). The donning layer is defined in the specification as also being a thin layer in the same manner as the barrier layer and therefore would be present in an amount within the claimed range of 0.3 mass% and 1 mass%. The acrylic

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polymer is defined in the specification in column 5, lines 29-61 as being an acrylic polymer defined in U.S. Pat. No. 5,712,346 to Lee. Lee teaches that the glass transition temperature of the acrylic polymer is about 15°C or greater up to 60°C (col.6, 1.13-16). The embodiment in which the acrylic polymer is about 15°C is within the claimed range of -30°C to 30°C and the claimed range of -20°C to 20°C. Regarding claims 14-17, the glove of Williams is formed of the same materials as the claimed invention. Therefore, the length of time of the resistance to 70% isopropyl alcohol is inherently greater than 120 minutes since the same material must have the same properties.

Claim Rejections - 35 USC § 103

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (US 2003/0115659 A1) in view of Lee (USPN 5,712,346).

Williams in combination with the incorporation by reference of Lee teaches all that is claimed in claim 10 as shown above, but fails to explicitly teach the glass transition temperature falling within the claimed range of -10°C and 10°C. However, Lee teaches that the acrylic polymer has multiple glass transition temperatures because the acrylic polymer is a copolymerization of different acrylic monomers so that one glass

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transition temperature would fall within the claimed range of -10°C and 10°C (col.7, 1.33-45). Lee goes on to teach that the exact glass transition temperature for the acrylic polymer is determined based on the desired end result of the acrylic polymer with regards to mold release characteristics and donning characteristics (col.7, 1.60-67). Also if the glass transition temperature is too high flaking will occur and if the glass transition temperature is too low then sticking and blocking will occur (col.8, 1.1-9). One of ordinary skill in the art would have recognized a glass transition temperature for acrylic polymer used in the formation of powder-free medical gloves would be selected through routine experimentation depending on the intended end result of the glove with regards to mold release, donning, flaking, and blocking characteristics, as taught by Lee.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select the glass transition temperature of the acrylic polymer of Williams within the claimed range depending on the intended end result of the glove especially with regards to mold release, donning, flaking, and blocking characteristics, as taught by Lee.

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8. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishi et al (USPN 6,012,169) in view of Lee (USPN 5,712,346).

Nishi et al teach a glove comprising a substrate body comprising polyvinyl chloride and a barrier layer overlying at least a portion of the substrate body, the barrier layer comprising an acrylic polymer (see abstract). The barrier layer is present in an amount that falls within the claimed range of 4 mass% to about 6 mass% of the glove (see the ratio of thickness of the base layer to the barrier layer taught in col.3, 1.7-8 and 1.45-46). The barrier layer is provided on the inner surface of the base layer so it is a skin-contacting layer. The barrier layer is formed of a different material so it is visually distinct from the substrate body.

Nishi et al fail to teach that the acrylic polymer has a glass transition temperature from about -30°C to about 30°C. However, Lee teaches that the exact glass transition temperature for an acrylic polymer used in the formation of a medical glove is determined based on the desired end result of the acrylic polymer with regards to mold release characteristics and donning characteristics (col.7, 1.60-67). Also if the glass transition temperature is too high flaking will occur and if the glass transition temperature is too low then sticking and blocking

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will occur (col.8, 1.1-9). One of ordinary skill in the art would have recognized a glass transition temperature for acrylic polymer used in the formation of powder-free medical gloves would be selected through routine experimentation depending on the intended end result of the glove with regards to mold release, donning, flaking, and blocking characteristics, as taught by Lee.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select the glass transition temperature of the acrylic polymer of Nishi et al within the claimed range depending on the intended end result of the glove especially with regards to mold release, donning, flaking, and blocking characteristics, as taught by Lee.

9. Claims 6-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishi et al in view of Lee as applied to claim 1 above, and further in view of Horwege et al (WO 95/17107 A1).

Nishi et al and Lee teach all that is claimed in claim 1 as shown above. Note claim 10, which is an independent claim, includes the limitations of claim 1 in combination with a donning layer comprising polyurethane overlying at least a portion of the barrier layer. Nishi et al and Lee taken as a

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whole fail to teach a donning layer in combination with the substrate body and barrier layer previously taught. However, Horwege et al teach that gloves formed from polyvinyl chloride require release powders. Horwege et al also teach that release powders used in gloves can cause allergic reactions and interfere with procedures that the user is conducting while wearing the glove (p.2, 1.1-6). Horwege et al teach that in order to form a donnable polyvinyl chloride glove without required release powders, a skin-contacting polyurethane layer is formed on the inner surface of the glove (p.3, 1.9-17). One of ordinary skill in the art would have recognized that a donning layer of polyurethane is added to the inner skin-contacting surface of a glove, in order to render the glove donnable without the need for release powder, as taught by Horwege et al.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add a donning layer of polyurethane to the innermost skin-contacting surface of the glove of Nishi et al and Lee, in order to render the glove donnable without the need for release powder, which can interfere with procedures in which the gloves are being used and/or cause allergic reactions, as taught by Horwege et al.

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Regarding claims 8 and 9, it is understood from the reading of Horwege et al that the thickness of the glove is determined solely by the thickness of the polyvinyl chloride layer especially with regard to page 11, lines 6-9 and page 17, lines 2-3. Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that the donning layer is present in the glove in an amount that falls within the claimed range of 0.3 mass% and 1 mass%.

Regarding claims 14-17, the glove of Nishi, Lee, and Horwege et al is formed of the same materials as the claimed invention. Therefore, the length of time of the resistance to 70% isopropyl alcohol is a latent property of the glove because the same material must have the same properties, and mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention (MPEP 2145).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lee (USPN 6,284,856); Vistins et al (US 2005/0015846 A1); Seketa (USPN 5,442,816).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to

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Christopher P. Bruenjes whose telephone number is 571-272-1489.

The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB *CB*
October 26, 2005

Harold Pyon
HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

10/31/05